RANDOMISATION FORM TRAPEZE

Please complete form before telephoning the Randomisation Service on ☎: 0800 731 7625 (Mon-Fri 9am-5pm)

Callers name (please print):	☎:	**Fax:**

Patient's Initials: ☐☐☐ (First middle last) **Date of Birth:** ☐☐ ☐☐☐ ☐☐☐☐ (dd/mmm/yyyy) **Sex:** Male ☐ Female ☐

Hospital No: ☐☐☐☐☐☐☐☐☐☐ **NHS No:** ☐☐☐☐☐☐☐☐☐☐

Randomising Hospital:

Randomising Consultant:

Hospital where Docetaxel will be given:
(If different from randomising hospital)

Hospital where Strontium-89 will be given
(If different from randomising hospital)

NB: Shaded boxes on this form indicate that patient is ineligible for study.

Patient Eligibility ***(Please confirm all the following statements are true by ticking each" yes" box)***

	YES	NO
• Histologically/cytologically proven prostate adenocarcinoma OR Multiple sclerotic bone metastases with PSA≥ 100ng/ml without histological confirmation.	☐	☐
• Radiological evidence of bone metastasis	☐	☐
• No hormonal drug therapy at least four weeks prior to enrolment and adverse events resolved.	☐	☐
• Documented progression	☐	☐
• Life expectancy ≥ 3 months	☐	☐
• Age ≥18 years	☐	☐
• Adequate haematological function (Hb ≥10g/dl, Neut ≥1.5 x 10^9/l, Plt ≥ 100 x 10^9/l)	☐	☐
• Adequate renal and hepatic function (Creat ≤ 1.5 x ULN, ALT & AST≤ 1.5 x ULN, Bili ≤ 1.5 x ULN)	☐	☐
• Written informed consent	☐	☐
• No prior cytotoxic chemotherapy for HRPC, except estramustine monotherapy	☐	☐
• No prior radionuclide therapy for HRPC	☐	☐
• No prior radiotherapy to >25% of the bone marrow (whole pelvic irradiation is not allowed)	☐	☐
• No prior treatment with bisphosphonate for any reason within previous two months	☐	☐
• No malignant disease within the previous 5 years, other than adequately treated basal cell carcinoma	☐	☐
• No known brain or leptomeningeal metastases	☐	☐
• No pre-existing neuropathy grade >2	☐	☐
• No known hypersensitivity to bisphosphonates	☐	☐
• No concurrent enrolment in any other investigational compound within previous 30 days	☐	☐
• No treatment with any other investigational compound within previous 30 days.	☐	☐
• No condition which, in the opinion of the investigator, might interfere with the safety of the patient or evaluation of the study objectives.	☐	☐

Intended start date of chemotherapy *(within 14 days of randomisation)*: *(dd/mmm/yyyy)* ☐☐ ☐☐☐ ☐☐☐☐

Please indicate *by ticking appropriate box* ECOG Performance status

0	1	2	3	4	5

Has patient consented to QoL study ☐ Yes ☐ No. If **'yes'**, has patient filled out a QoL booklet ☐ Yes ☐ No

Has patient consented to biological proteomic study ☐ Yes ☐ No

Has patient consented to tumour block collection ☐ Yes ☐ No

On randomisation please complete the following:

Trial number allocated: **Paper Randomisation: Yes ☐ No ☐**

Treatment allocation : ***(tick a box below)*** ***(if yes please enter time):*** ☐☐ ☐☐

☐ Docetaxel + prednisolone

☐ Docetaxel + prednisolone + zoledronic acid

☐ Docetaxel + prednisolone+ Strontium-89

☐ Docetaxel + prednisolone + zoledronic acid + Strontium-89

Signature **Randomisation Date** ☐☐ ☐☐☐ ☐☐☐☐